

## **Considerations for Dispensing Controlled Substance Prescriptions**

### **Introduction**

As you have likely heard, the DEA has been placing an increased emphasis on controlled substance diversion, especially diversion involving community pharmacies. For purposes of this document, diversion refers not only to outright theft and forged or fraudulent prescriptions, but also to prescriptions that are not written for a legitimate medical purpose.

Walmart remains committed to patient safety and strict regulatory compliance, and as such wants to reiterate our focus on the appropriate dispensing of controlled substances. As the DEA continues to investigate controlled substance diversion, they have identified a number of “red flags” that, when present, indicate a need for further evaluation and may ultimately lead to a pharmacist’s professional judgment that a particular prescription should not be dispensed.

It is important to consider each of these characteristics for every controlled substance that is brought to your pharmacy. In the course of your practice, you will likely encounter many of these “red flags” pertaining to prescriptions. The presence of a “red flag” may indicate that the prescription should not be filled however this may not always be the case. Sometimes, “red flags” can be resolved through using your available resources and through communication with the patient, prescriber, and/or other pharmacists. Regardless, each *flag* must be evaluated thoroughly before deciding to dispense or deny a controlled substance prescription.

To help you evaluate each controlled substance prescription, the “red flags” are divided into three categories:

- Prescriber Red Flags – Those concerns arising from the specific prescriber and how he or she tends to prescribe in the course of practice.
- Patient Red Flags – Those concerns arising from the patient, and his or her filling habits.
- Prescription Red Flags – Those concerns specifically about the characteristics of the prescription.

Each “red flag” listed has been identified previously by the DEA in connection with one or more investigations in diversion cases. This is not an all-inclusive list of considerations for appropriate dispensing of controlled substances, but rather a starting point as you apply your professional judgment in the course of your practice to thoroughly evaluate all controlled substance prescriptions.

### **Corresponding Responsibility**

While there are many laws, both state and federal, regulating controlled substances, one regulation in particular must always be considered when approaching the decision to fill a controlled substance prescription. Often simply referred to as a pharmacist’s “corresponding responsibility,” 21 C.F.R. § 1306.04(a), states:

“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The

responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist who fills the prescription.** “

This regulation is interpreted by federal agencies to mean that, as pharmacists, there is a legal responsibility not to dispense controlled substance prescriptions that were not written for a legitimate purpose. This regulation is also used as the basis for nearly all criminal action taken by the DEA against pharmacies and pharmacists, and therefore should be one of the guiding principles by which you make decisions in your pharmacy surrounding controlled substance dispensing.

### **Take Action**

1. Prior to dispensing a controlled substance prescription, use your professional judgment to evaluate **each and every** prescription for appropriateness, both from a patient safety perspective and a diversion perspective.
2. Think of the three “red flag” areas as three lenses to evaluate each prescription:
  - a. Is there anything about this specific prescriber that is of concern?
  - b. Are there characteristics of this patient and his or her profile that raise a concern?
  - c. Are there factors about this prescription that indicate it may not be appropriate?
3. Use the available resources to ensure all applicable laws and Walmart policies are being followed.

### **Pharmacist Obligations**

1. Always use professional judgment to evaluate all prescriptions you receive.
2. Never let a business metric come before your professional judgment. Patient safety and providing quality patient care are always our first priority.
3. Report all denied prescriptions using the Forged or Fraudulent Prescription Activity Webform on the WIRE (See POM 1311).

### **DEA Red Flags**

In the table below, DEA-identified “red flags” are highlighted along with important considerations and resources that should be evaluated when evaluating controlled substance prescriptions.

For each “red flag”, use your professional judgment and the available resources to determine if there is a valid reason for the presence of the “red flag” or if the “red flag” is indeed indicative of a potentially inappropriate prescription. All “red flags” should be evaluated and resolved prior to dispensing a controlled substance prescription.



Prescriber Factors	
<b>1. Prescription is written by a prescriber outside of the pharmacy's trade area.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>○ Why is the patient traveling a far distance for the specific prescriber?</li> <li>○ Does the prescriber practice in a specialty not available locally?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>○ POM 1311</li> <li>○ POM 1317</li> <li>○ Patient Profile</li> <li>○ Prescriber Consultation</li> </ul>
<b>2. Prescriber routinely prescribes large number (or percentage) of prescriptions for controlled substances relative to prescriptions for non-controlled substances.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>○ Is the prescriber in a specialty, such as oncology or pain management, that traditionally writes for large numbers of controlled substances?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>○ Prescriber Files</li> <li>○ Knowledge of the local area</li> </ul>
<b>3. Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>○ Is the dose of medication higher than maximum recommended dose and/or if combined with the patient's other prescriptions would result in a higher than recommended daily dose?</li> <li>○ Does the patient have a medical condition that may warrant higher doses?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>○ Patient Files</li> <li>○ Patient Consultation</li> <li>○ POM 1311</li> </ul>
<b>4. Prescriber routinely writes for large doses of controlled substances.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>○ Is the dose of medication on the given prescription out of the ordinary or if combined with a patient's other prescriptions would result in an unreasonably large daily dose?</li> <li>○ Does the patient have a medical condition that may warrant higher doses?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>○ Drug Reference</li> <li>○ Patient Files</li> <li>○ Patient Consultation</li> <li>○ Prescriber Consultation</li> </ul>
<b>5. Prescriber provides the same diagnosis for the majority of individuals.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>○ Is the prescriber in a specialty that treats a narrow set of conditions?</li> <li>○ Is the prescriber in a specialty, such as oncology or pain management, that traditionally writes for large numbers of controlled substances?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>○ POM 1311</li> <li>○ Prescriber Consultation</li> </ul>
<b>6. Prescriber engages in the unauthorized practice of medicine, including writing prescriptions outside of scope of practice and/or not having a proper relationship with the patient.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>○ Is the medication prescribed within the scope of practice of the prescriber? For example, is a pediatrician writing for an adult patient, or is a dentist prescribing for chronic pain?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>○ POM 1311</li> <li>○ POM1319</li> <li>○ Prescriber Consultation</li> </ul>

Patient Factors	
<b>1. Individual insists on paying cash, or insists on paying cash for controlled substances even though insurance is on file.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>Does the patient have insurance? If so, is there a reasonable cause for them to request paying cash?</li> <li>Does the patient use his or her insurance for other prescriptions, but exclude controlled substances?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>POM 1311</li> <li>POM 1316 (when applicable)</li> <li>Patient Profile</li> </ul>
<b>2. Evidence of “doctor shopping” exists.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>Are multiple prescribers being seen by the patient in the same period of time?</li> <li>Is the prescription from a group practice where one prescriber might share a patient panel with another?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>POM 1311</li> <li>POM 1316 (when applicable)</li> <li>Prescriber Consultation</li> </ul>
<b>3. Evidence of “pharmacy shopping” exists.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>Is the patient filling solely controlled substances at the pharmacy?</li> <li>Is there a genuine reason (e.g., work travel) for the patient visiting multiple pharmacies?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>POM 1311</li> <li>POM 1316 (when applicable)</li> <li>Prescriber Consultation</li> <li>Local Pharmacy Outreach</li> </ul>
<b>4. Individual resides outside of the trade area of your pharmacy.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>Is there a genuine reason (e.g., work travel) for the patient visiting multiple pharmacies?</li> <li>Is there a pattern indicating “pharmacy shopping”? Is the prescriber also from a different location?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>POM 1311</li> <li>POM 1316 (when applicable)</li> <li>POM 1317</li> <li>Prescriber Consultation</li> </ul>
<b>5. The individual’s statements and conduct or behavior suggest abuse of controlled substances.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>Does the patient appear to be under the influence of intoxicating substances?</li> <li>Is the patient using language or making statements that suggest abuse, such as using street names of medications or asking for extra pills?</li> <li>Does the patient ask for specific manufacturers or pills with certain colors or markings?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>Patient profile</li> <li>Prescriber consultation</li> <li>POM 1318</li> </ul>
<b>6. Individual routinely attempts to obtain an early refill on controlled substances.</b>	
<b>Ask:</b> <ul style="list-style-type: none"> <li>Has the patient received the prescription early routinely?</li> <li>Has there been a dosing change that requires a new prescription?</li> </ul>	<b>Use:</b> <ul style="list-style-type: none"> <li>POM 1318</li> <li>Patient consultation</li> <li>Patient profile</li> <li>Prescriber consultation</li> </ul>



**7. Individuals have suspicious relationships with each other.****Ask:**

- Are multiple patients filling prescriptions from one address?
- Are prescriptions being presented by someone other than the patient? Is there a reason for this such as a caregiver, etc.?
- Are groups of patients arriving all with the prescriptions for the same medication from the same doctor?

**Use:**

- POM 1311
- POM 1316 (when applicable)

**Prescription Factors****1. Prescriptions presented represent a “cocktail” of commonly abused drugs or are presented in a combination that can cause medical complications.****Ask:**

- Could the prescriptions presented (or already present on the patient’s profile) put the patient at risk if taken together?
- Is there a legitimate medical reason for the use of the combination?
- Is there a trend in your area of abuse of a certain cocktail or drug?

**Use:**

- POM 1311
- Patient Profile

**2. Prescription presented is for an unusually large quantity or high starting dose.****Ask:**

- Does the patient have a medical condition that may require the need for high-dose medications, such as chronic pain or oncology?
- Has the patient been on a similar or escalating regimen previously?

**Use:**

- POM 1316
- Patient Profile
- Prescriber Consultation

**3. Prescription appears to be altered or duplicated.****Ask:**

- Does the prescription meet any of the criteria in POM 911 or have any other indication of the presence of forgery or alteration?

**Use:**

- Prescriber consultation
- POM 911

**This list does not cover all situations you may encounter in your practice; in all cases, use your professional judgment and available resources to determine the appropriateness of any controlled substance prescription before you make the decision to dispense the medication.**

**Available Resources:**

- Pharmacy Operations Manual, in particular:
  - POM 203: Pharmacist Responsibility
  - POM 911: Diversion SOP
  - POM 1311: Proper Prescriber-Patient Relationship
  - POM 1316: Prescription Monitoring Programs
  - POM 1317: Controlled Substance Prescriptions Written by Out-of-State Prescribers

- POM 1318: Early Refill of Controlled Substance Prescriptions
  - POM 1319: Prescriber Information
  - POM 1703: Forged or Fraudulent Prescription Procedures
- State Prescription Monitoring Programs
- Connexus Patient Profiles
- Peer Pharmacist Consultation
- Prescriber Consultation
- Patient Consultation
- Market Health & Wellness Directors
- Health & Wellness Practice Compliance